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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,750	01/16/2001	Ichiro Azuma	0020-4802P	7730

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,750	AZUMA ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-8,10,11 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2005 has been entered. Applicant's submission of the declaration by Dr. Nomura filed under 37 CFR 1.132 and the journal article by Zhar et al (*J Nat. Cancer Inst. 48:831-835, 1972)* are acknowledged. The declaration submitted by Dr. Kawabe filed under 37 CFR 1.132 was filed April 6, 2005. Claims 1-3, 5-8, 10-11 and 13-20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 4 and 12 have been cancelled.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

It should be noted that Applicant has incorporated by reference the response filed April 6, 2005 in its entirety to address the rejections of record.

Rejections Maintained

3. The rejection under 35 U.S.C. 102(b) is maintained for claims 21 and 23-26 for the reasons set forth on pages 3-6 paragraph 5 of the Final Office Action.

The rejection was on the grounds that Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent (see the Abstract). Yamamura et al teach that cell wall skéleton used in the invention can be derived from *Mycobacterium bovis* (column 2, lines 15-21). Yamamura et al teach the composition was prepared using suspending agents such as Tween and Span (surfactants) (column 2, lines 54-68). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yamamura et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges that the Office misunderstands the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to give an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent.

Applicant's arguments filed July 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. It should be noted that Yamamura et al teach that the dispersed oil-attached CWS have a diameter of about 5 μ (column 4) which falls within the diameter range of the oil droplets in the claimed oil-in-water emulsion.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-

CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided. Although a solvent such as ethanol or toluene is used in the process of making the claimed emulsion, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration are not commensurate with the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

4. The rejection under 35 U.S.C. 102(b) is maintained for claims 21 and 23-26 for the reasons set forth on pages 6-8-paragraph 6 of the Final Office Action.

The rejection was on the grounds that Cantrell teaches vaccines comprising cell wall skeleton which is obtained from microorganisms including *Nocardia rubra* and *Mycobacterium bovis* (column 4, lines 54-68) and squalene (oil). Cantrell teaches that the oil is combined with a detergent (i.e. Tween or Arlacel) (surfactant) (column 7, lines 27-35). Cantrell teaches the formation of oil droplet emulsions (column 7, lines 35-40 and column 10). Claim limitations such as "wherein the emulsion is negative for

agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Cantrell anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges the Office misunderstands the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to give an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-

CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the CWS without the use of a solvent.

Applicant's arguments filed July 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Cantrell teaches compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent. Cantrell teaches that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided. Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 9).

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS

suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration are not commensurate with the claimed invention which is directed to a oil-in-water emulsion and not a method of preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 21 and 23-26 for the reasons set forth on pages 8-10 paragraph 7 of the Final Office Action.

The rejection was on the grounds that Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yarkoni et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material

structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges the Office misunderstands the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to given an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent to prepare the BCG-CWS compositions and preparing the BCG-CWS without the use of a solvent.

Applicant's arguments filed July 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yarkoni et al teach compositions comprising *Mycobacterium bovis* BCG cell wall skeleton, squalene, a suspending agent and dispersing agent. It should be noted that Yarkoni et al teach oil-droplets that have a diameter of greater than 1 μm (page 883) which falls within the diameter range of the oil droplets in the claimed oil-in-water emulsion.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to

prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided.

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration is not relevant to the claimed invention which is directed to a oil-in-water emulsion and not a method preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

6. The rejection under 35 U.S.C. 102(b) is maintained for claims 21-26 for the reasons set forth on pages 11-13 paragraph 8 of the Final Office Action.

The rejection was on the grounds that Van Nest et al teach compositions (oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets (see the Abstract). Van Nest et al teach that the composition of the invention comprise cell wall skeleton from *Mycobacteria* (column 9, lines 8-15). Van Nest et al teach that the oils used in the composition include squalene (column 4, lines 45-48). Van Nest et al teach that emulsifying agents include in the composition include ethanol (column 10, lines 58-63). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not

changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Van Nest et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended and the properties of the claimed invention are defined in claim 21. Applicant urges that Office misunderstands the technical features of the present invention especially effects of "an organic solvent" used during the preparation of the emulsion. Applicant urges that an organic solvent is used to mix BCG-CWS and oil and then the organic solvent is evaporated off to give an intended emulsion. Applicant refers to the two Declarations filed under 37 CFR 1.132 of Dr. Nomura and Dr. Kawabe. Applicant urges that the declarations are submitted to demonstrate the difference in particle size of the BCG-CWS composition using a solvent and preparing the BCG-CWS without the use of a solvent.

Applicant's arguments filed July 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Van

Nest et al teach stable compositions comprising oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets. Van Nest et al teach that the composition of the invention comprise cell wall skeleton from *Mycobacteria*. It should be noted that Van Nest et al teach oil-droplets that have a diameter of 1-2 microns and 10 microns (column 13) which falls within the diameter range of the oil droplets in the claimed oil-in-water emulsion.

To address Applicant's comments regarding the Declaration of Dr. Nomura, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. However, the declaration does not compare the oil-in-water of the prior art with the instantly claimed oil-in-water emulsion. There is no evidence provided to show that the claimed emulsion differs from that of the prior art since no comparison has been provided. Although the use of a solvent such as ethanol or toluene is used in the process of making the claimed emulsion, it should be noted that the prior art teaches that ethanol and acetone were both used in the preparation of the cell wall components of the oil-in-water emulsion (column 10).

To address Applicant's comments regarding the Declaration of Dr. Kawabe which is submitted to show the differences between the morphologies of BCG-CWS suspended in a solvent (e.g. toluene) and the morphologies of BCG-CWS suspended in saline, it appears the data in this declaration are not commensurate with to the claimed

invention which is directed to a oil-in-water emulsion not a method of preparing an emulsion.

There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

New Ground of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

It should be noted that the Examiner is viewing the claimed invention as oil-in-water emulsion comprising Bacillus Calmette-Guerin (BCG) cell wall skeleton. Claim limitations directed to preparing the emulsion are being viewed as process limitations.

7. Claims 21 and 23, 24 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by Zbar et al *(Journal of National Cancer Institute, Vo. 48, No.3, p. 831-835).*

Claims 21 and 23, 24 and 26 are drawn to an oil-in-water emulsion wherein the emulsion is negative for agglutination reaction with lectin and a Bacillus Calmette-Guerin cell wall skeleton is encapsulated in an oil and the diameter of an oil droplet is 100 μm or less which emulsion is obtained by the following steps: (a) stirring a mixture of a Bacillus Calmette-Guerin cell wall skeleton, an oil, and an organic solvent to disperse the Bacillus Calmette-Guerin cell wall skeleton in the mixture; (b) evaporating

off the organic solvent to form an oil wherein the Bacillus Calmette-Guerin cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is encapsulated in the oil; and then, (c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture.

Zbar et al teach compositions comprising BCG cell walls and mineral droplets (see the Abstract and pages 831-832). Zbar et al teach that the oil droplets of the prior art ranged from less than 1 μ to greater than 15 μ. Therefore, the claim limitation "the particle diameter of an oil droplet is 100 μm or less taught by the prior art. The claim limitation wherein the emulsion is negative for agglutination reaction with lectin" would be inherent in the teachings of the prior art. Claims limitations such as "(a) stirring a mixture of a Bacillus Calmette-Guerin cell wall skeleton, an oil, and an organic solvent to disperse the Bacillus Calmette-Guerin cell wall skeleton in the mixture; (b) evaporating off the organic solvent to form an oil wherein the Bacillus Calmette-Guerin cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is encapsulated in the oil; and then, (c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture" are being viewed as process limitations. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by

the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Zbar et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

8. No claims allowed.

Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Examiner
August 24, 2005

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600